



Comptroller General
of the United States

404169

Washington, D.C. 20548

Decision

Matter of: Roche Diagnostic Systems, Inc.

File: B-255578.4

Date: September 16, 1994

Steven S. Diamond, Esq., Walter F. Zenner, Esq., and Lesley R. Frank, Esq., Arnold & Porter, for the protester. Michael T. Janik, Esq., and Mark J. Meagher, Esq., McKenna & Cuneo, for Immunalysis Corporation, an interested party. Demetria T. Carter, Esq., and John R. Osing, Esq., Department of the Navy, for the agency. Richard P. Burkard, Esq., and John Van Schaik, Esq., Office of the General Counsel, GAO, participated in the preparation of the decision.

DIGEST

1. Agency reasonably concluded that awardee's proposal to provide drug test kits was technically acceptable where, although one set of test data submitted by the awardee to the agency indicated that the kit may not comply with a mandatory specification, other test data submitted by awardee showed compliance with the specification.
2. Protest that awardee's product did not comply with Food and Drug Administration (FDA) approval requirement contained in solicitation is denied where FDA, after independently reviewing the allegation advised that the awardee's product complies with the requirement.

DECISION

Roche Diagnostic Systems, Inc. protests the award of a contract to Immunalysis Corporation under request for proposals (RFP) No. N62645-93-R-0025, issued by the Department of the Navy for radioimmunoassay drug test kits. Roche alleges principally that based upon test data submitted to the Navy, the Immunalysis kit will not comply with a mandatory RFP requirement and that the proposal should have been rejected as technically unacceptable. The protester also contends that the awardee's kit did not comply with Food and Drug Administration (FDA) approval requirements.

We deny the protest.

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The RFP contemplated the award of a firm, fixed-price, indefinite quantity, indefinite delivery contract for a base year with 2 option years. The kits supplied will be used by the Navy, Army, and Air Force to detect the use of marijuana by active duty personnel. The RFP provided that the agency would make award to the offeror which submitted the low-priced, technically acceptable offer.

The RFP provided that the "test kit shall be a radioimmunoassay for cannabinoids." The kits consist of three basic operative ingredients called reagents: (1) a radioactive antigen; (2) a first antibody; and (3) a second antibody. To use the kit, the three reagents are mixed together in a test tube containing a urine specimen. At the end of the testing process, a radioactive pellet is formed and the radioactivity of the pellet is measured by a gamma counter in counts-per-minute. The counts-per-minute reading is then compared with the counts-per-minute readings of prefabricated specimens, or "standards," which contain a concentration of the target drug at the "cut-off" level, that is, the level below which a specimen is considered to test negative and above which a specimen is considered to test positive.

In typical use, samples are analyzed in large groups or "batches." To ensure that the kits are performing uniformly and that the assay remains properly calibrated throughout the testing procedure, each batch includes "high control" samples and "low control" samples. The "low control" samples contain a known concentration of the target drug which is below the "cut-off" level, while the "high control" sample contains a known concentration above the "cut-off" level.

Among numerous other technical requirements set forth in the RFP, the agency sought to ensure that specimens containing identical concentrations of the target drug yield uniform results throughout a batch of samples to be tested. The RFP provided that the "precision of replicate readings for the standard and any controls, either within a single rack or distributed throughout a batch . . . shall have a coefficient of variation [CV] less than 5.0 percent using a 0.2 minute counting time." The agency explains that this requirement was included in the RFP "to limit the degree of permissible drift during an entire run of testing." For brevity's sake, we refer to this requirement as the CV requirement.¹

¹As discussed below, the agency subsequently amended the RFP to clarify that the CV requirement applied across all tubes in a batch, regardless of their placement.

Three offerors, including Roche and Immunalysis, submitted price and technical proposals by the August 9, 1993, closing date. In accordance with the RFP, the agency used a two-step process to evaluate "the essential characteristics of the assay," including the CV requirement. Both steps required that the offerors "submit radioimmunoassay data from a single run that included the analysis of replicates at specified drug concentrations." Step 1 contemplated that the offerors would submit data based on testing 8 groups, each containing 10 samples, which each of the offerors were to provide themselves. Groups 1 and 8 each contained 10 samples containing the "cut-off" concentration of cannabinoids in urine; groups 2 and 9 each contained 10 samples containing "high control" concentrations; groups 3 and 6 each contained 10 "negative" samples containing no cannabinoids; and groups 4 and 7 each contained 10 samples containing "low control" concentrations.² Among other things, review of the data submitted was to assure the agency that the offeror's kit complied with the CV requirement for the control groups, i.e., to assure that the kit measures samples containing identical concentrations of cannabinoids consistently throughout a batch.

Both Roche and Immunalysis submitted data under step 1 of the evaluation showing compliance with the CV requirement. The agency therefore proceeded with the step 2 evaluation. Under this step, offerors were to test and analyze another batch of samples that included the eight groups described above. As in step 1, the offerors were to provide those samples themselves. In addition, for step 2, the agency provided the offerors with urine samples to be analyzed as group 5. The offerors were to identify each sample as positive or negative and submit supporting data as they had done under step 1. Immunalysis correctly identified each of the samples as positive or negative. The data submitted, however, showed that the "high control" readings in group 2 varied from those in group 9 by more than 5 percent. Thus, the Immunalysis data did not show compliance with the CV requirement with regard to "high control." The Roche data, too, failed to show compliance with the CV requirement. In addition, Roche failed to accurately identify a number of the government-provided specimens as positive or negative.

Although the Navy initially eliminated both firms from further consideration based on the step 2 data, the agency ultimately chose not to consider the step 2 data and to include both firms in the competitive range. While both

²No group 5 was included in step 1.

firms offered explanations³ for the step 2 failures, the agency states that these explanations were not considered since the technical panel recognized that the type of assay being purchased here occasionally fails in the normal course of business, even in military laboratories. In addition, the Navy had successfully purchased these kits in the past without using the step 2 procedures, and repeating the step would be expensive and time-consuming. Therefore, and given that both Roche and Immunalysis would benefit from discarding the step 2 data, the Navy did so and proceeded with discussions with those firms.

During discussions, the agency advised Immunalysis in writing that "there was no definitive statement provided that the assay would meet the specifications for reproducibility of responses from calibrators and controls when 320 tubes are used in the assay in accordance with [the RFP specifications]." Immunalysis responded that its kit "does meet the specifications for reproducibility of responses from calibrators and controls when 320 tubes are used in the assay. . . ." Immunalysis provided two additional sets of data showing data for calibrators and controls run in a 320 tube assay. The agency found that the "CV's were all well within the tolerances of the specifications and that there were no indications of a problem with drift throughout the assay." The agency requested and received best and final offers from Immunalysis, Roche, and one other firm. Immunalysis submitted the low offer at \$2,325,918. The agency considered the Immunalysis kit to be acceptable and consequently awarded that firm the contract.

Roche argues primarily that it was unreasonable for the Navy to determine Immunalysis's proposal to be technically acceptable in the face of the inconsistent test data that the firm submitted. The protester asserts that, notwithstanding the data which purports to show compliance, the step 2 data demonstrated that the Immunalysis assay does not comply with the CV requirement and that it was arbitrary and irrational for the Navy to discard the Immunalysis step 2 test failure without considering the reasons for the failure. Roche contends that the step 2 data demonstrates that the Immunalysis kit was fundamentally flawed and points to an earlier protest of this RFP filed by Immunalysis in which that firm complained about the agency's interpretation of the RFP concerning use of the step 2 data. Specifically, Immunalysis questioned the propriety of comparing groups

³Roche stated that its failure was due to an equipment failure during the tests, while Immunalysis stated that the different groups yielded inconsistent results because of differing incubation times.

2 and 9 for purposes of determining compliance with the CV requirement. In its protest, Immunalysis stated that because of the different incubation periods, group 2 "high control" readings should not be compared to group 9 "high control" readings, which occurred later in the batch; rather, Immunalysis contended that only readings of samples in the same group should be compared. As Roche points out, the Navy rejected Immunalysis's interpretation and amended the RFP to clearly state that the CV requirement applies across groups. According to Roche, Immunalysis's arguments made before the clarification were, in effect, an admission of the inability of its kit to comply with the CV requirement across groups.

While Roche attempts to highlight the significance of the step 2 data and Immunalysis's interpretation of how that data should be analyzed, the real question here, in our view, is whether the evaluation, which included review of data from the step 1 and 2 test runs, the proposal, and the supplemental data supplied by Immunalysis, was adequate for the agency to reasonably determine that Immunalysis will supply test kits meeting the RFP requirements. An agency's evaluation of technical proposals is primarily the responsibility of the contracting agency; the agency is responsible for defining its needs and the best method of accommodating them, and must bear the burden of any difficulties resulting from a defective evaluation. Steward-Davis Int'l, Inc., B-250254; B-250254.2, Dec. 17, 1992, 92-2 CPD ¶ 423. Thus, our Office will not make an independent determination of the merits of technical proposals; rather, we will examine the agency's evaluation to ensure that it was reasonable, and consistent with stated evaluation criteria and applicable statutes and regulations. Id.

With respect to agency use of test data as an extension of the technical evaluation of proposals, we have held that the results of operational or benchmark tests are "strong evidence" of the capability of the tested item which must be considered in the determination of technical acceptability. Rand McNally-TDM, Inc., B-248927, Oct. 7, 1992, 92-2 CPD ¶ 352. On the other hand, we have long been critical of tests in which the strict application of pass/fail criteria leads to the automatic exclusion of a potentially acceptable proposal. QAO Corp.; 21st Century Robotics, Inc., B-232216; B-232216.2, Dec. 1, 1988, 88-2 CPD ¶ 546.

Here, we find the agency's judgment that the Immunalysis kit complies with the CV requirement to be reasonably based on all the information it had obtained. In this regard, two of the three sets of data examined by the agency in reaching its conclusion showed that the Immunalysis kit was

acceptable.⁴ Only the step 2 data, which was not considered for either offeror, indicated difficulty in meeting the requirement. While the protester contends that this failure was significant and that it was unreasonable for the agency to make award to Immunalysis without first determining the precise cause of the step 2 failure, the agency attributed the failure to a normal failure rate, and given the previous step 1 data, did not seek explanations for the failure.

Moreover, as stated, the agency obtained an assurance from Immunalysis that its kit, in fact, would comply, and received supplemental data from Immunalysis showing compliance with the CV requirement. The supplemental data was based on two separate 320 tube runs, which included 240 "group 5" samples and demonstrated that the precision of values from the assay of the tubes containing the "high control" samples had a CV of less than 5 percent across all "high control" samples as required by the RFP. The evaluators found the data to be "particularly convincing because of the good precision of the assay and the consistency with previous results."

The evaluators noted also that the kit was already being used in military drug testing laboratories under a previous contract and was performing successfully. Under the circumstances, we cannot say it was unreasonable for the Navy to discount the failure of Immunalysis's kit in step 2.

⁴The protester argues that the step 2 data is more credible than the supplemental data provided by Immunalysis since, under step 2, the government, and not the offeror, provided the samples to be examined. This argument is without merit since in both the step 2 and the supplemental test, the "high controls," which are prefabricated urine samples, were prepared by the offeror. The fact that the government supplied samples to be tested in step 2 is essentially irrelevant to Immunalysis's failure to meet the CV requirement under step 2, as that failure did not directly involve the government-supplied samples. Moreover, although Roche argues that Immunalysis's supplemental data showing compliance was generated under "essentially unspecified conditions," and therefore lacked credibility, none of the three test runs was conducted under the supervision of the agency. We therefore fail to see how the step 2 data was inherently more reliable than the supplemental data. We note additionally that even though the Immunalysis kit failed the CV requirement in step 2, it accurately identified the government-supplied samples, while the Roche kit did not.

While the agency could have tested the Immunalysis kit further, agencies are given considerable discretion to establish the tests or procedures necessary to determine product acceptability, and we will not disturb the agency's determination unless it is shown to be unreasonable. Wild & Leitz Technologies Corp., B-224302, Nov. 12, 1986, 86-2 CPD ¶ 552. Here, the RFP did not specify that failure to meet any requirement during either step would require rejection of the proposal or retesting, and given the circumstances, including the sufficiency of the supplemental data as well as the time and expense of conducting another step 2 evaluation, the agency could properly choose not to continue testing or otherwise attempt to resolve the apparently inconsistent test results.⁵ In this regard, even if testing requirements are waived, the waiver does not affect the offeror's obligation to furnish supplies conforming to all of the RFP specifications. OAO Corp.; 21st Century Robotics, Inc., supra. In short, we do not think that the step 2 results compelled rejection of the proposal or further testing. Rather, in our view, the agency had sufficient information to make a reasoned judgment that the Immunalysis kit will comply with the CV requirement.

Concerning the protester's contention that Immunalysis's post-step 2 protest to our Office constituted an admission that the Immunalysis kit cannot comply with the CV requirement, we do not think that the correspondence can fairly be read as such an admission. While clearly Immunalysis argued that the RFP contemplated only a comparison of readings within groups and not across groups, it did not state that it was not capable of meeting the requirement across groups. The Immunalysis argument, in our view, focused on an alleged ambiguity in the solicitation, which was also pointed out by Roche and subsequently resolved by the agency. When the agency made clear in an RFP amendment that the CV requirement applied across groups, Immunalysis did not challenge that amendment and provided reasonable evidence that it could comply.⁶

Roche also argues that Immunalysis made changes to its kit during the evaluation process which were not approved by FDA

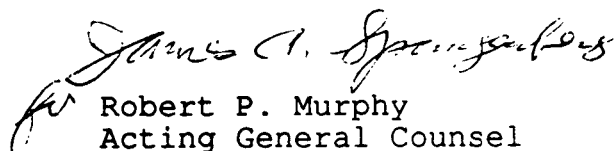
⁵As stated, since the agency initially had decided to reject both firms from further consideration based on the step 2 data, its decision to not consider the data benefitted both Roche and Immunalysis.

⁶Roche's argument also ignores the explanation offered by Immunalysis that the inconsistent results may have been attributable to disparate incubation times as well as the agency's explanation that failures of this sort are not uncommon.

as required by the RFP. The RFP provided that the kits are "medical devices and must have clearance from the [FDA] to be marketed." It stated further that "[a]ny changes to the FDA cleared kit shall be covered by resubmission of a [section] 510(k)," the FDA application for product approval.⁷ According to Roche, since Immunalysis undertook modifications to its product which "significantly affected" the effectiveness of the kit, FDA regulations require that the Immunalysis kit receive new 510(k) approval. 21 C.F.R. § 807.81(a)(3)(i) (1994). Without such approval, Roche argues, Immunalysis's test kit failed to satisfy a mandatory RFP requirement for FDA approval and was therefore ineligible for award. Both the Navy and the awardee contend that the modifications to the test kit were minor and not the type which triggered the requirement for resubmission of a 510(k).

We requested the views of the FDA concerning this protest allegation. After reviewing the relevant facts and positions of the parties, the FDA provided our Office with a written response concluding that the changes made to the Immunalysis kit did not require the submission of a new 510(k). Based on the FDA response, we conclude that the Immunalysis kit had the necessary approval from the FDA and that there was no need for Immunalysis to submit a new 510(k). To the extent Roche argues that the RFP required FDA review and approval of "any changes" to the proposed test kits (i.e., whether or not the modification significantly affected the kits), the protester has not shown, nor do we see how, under the circumstances, i.e., that FDA believes no further approval is necessary, Roche was prejudiced by Immunalysis' decision not to submit a new 510(k). See Roche Diagnostic Sys., Inc., B-255578.2, June 22, 1994, 94-1 CPD ¶ 375.

The protest is denied.


 Robert P. Murphy
 Acting General Counsel

⁷This terminology is based upon the relevant section 510(k) of the Federal Food, Drug, and Cosmetics Act, which is codified at 21 U.S.C. § 360(k) (1988).